REMARKS

Claims 1, 2, 6, and 10-16 are currently pending in the application. Claims 1, 10, and 15 are in independent form. New claim 26 has been added as suggested in the personal interview to specify that the detection device of claim 1 is a blood pressure detector. No new matter has been added.

Applicants wish to express their appreciation for the courtesies extended Applicants' representatives, Kenneth I. Kohn and Laura S. Dellal, during a personal interview conducted on October 16, 2008.

Claims 1, 10-12, and 14 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,623,443 to Polaschegg. Specifically, the Office Action holds that Polaschegg discloses a method and device for detection of stenosis in extracorporeal blood pressure measurement. The stenosis, such as in a graft or fistula, in a blood access circuit or in an extracorporeal circuit is detected by monitoring the pressure pulses in the extracorporeal circuit. Sensors mechanically attached to the wall of the blood tubing will monitor the pressure pulse amplitude. The pressure at the vicinity of the fistula, such as at the arterial puncture site 201 and the venous puncture site 203 is monitored via pressure sensors 40 and 42 continuously. The Office Action holds that the derived intravascular blood pressure is compared to a standard, during a procedure such as blood dialysis and the deviation of a pressure pulse amplitude signal from a predetermined value indicates stenosis. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Polaschegg patent, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Polaschegg measures and compares the amplitude of pressure pulses within the extracorporeal circuit in order to determine if a stenosis has occurred therein (abstract). More specifically, the peak-to-peak amplitude of the pressure waves created by variations in the patient's blood pressure and variations in pressure created by the extracorporeal blood pump are used to indicate the presence of an obstruction in the circuit. Figures 4 and 5 of Polaschegg show a simulation of the peak-to-peak measurements that indicate an occlusion. A deviation in the peak-to-peak amplitude of the pressure signal from a predetermined standard value indicates a stenosis or loss of occlusion of the roller pump. Polaschegg, however, does not define the standard needed to indicate a stenosis that represents a significant risk to the patient. Measurement of the parameters in Polaschegg is simple and occurs when the blood pump is stopped because of the machinery's interference with measurements (col. 5, lines 56-65). In other words, peak-to-peak amplitude measurements are easily obtained without complex calculations (unlike those of the present invention). Polaschegg refers to the prior art published by Frinak and Besarab (inventors of the present invention) to correct the peak-to-peak amplitude measurements for variations in the patient's blood pressure from treatment to treatment by calculating the ratio of the arterial pulse amplitude divided by the amplitude of the patient's blood pressure, systolic minus diastolic blood pressure pulses (col. 8, lines 35-36).

Before peak-to-peak amplitude analysis can be used as an effective technique for monitoring dialysis patients for the risk of access clotting, individual measurements must be compared to a standard with a clearly defined threshold for detecting a significant access stenosis. Polaschegg again refers to the prior art established by Frinak and Besarab to suggest that an arterial pulse amplitude ratio of

53% would indicate the need for an intervention in grafts to eliminate the stenosis (col. 8, lines 36-39). Polaschegg concludes by stating that the limit values have to be established in clinical practice.

The measurements taken in Polaschegg (pressure pulses) are not actually measurements of intracorporeal pressure. Polaschegg monitors pressures within the *circuit*, not calculating the intravascular blood pressure in proximity of the access location of the patient. While various pressures can be derived from the sensors in the circuit in order to determine the pressure pulse, such as pressures 40 and 42, the absolute intracorporeal pressure is not and cannot be measured by the method of Polaschegg. Furthermore, pressure sensors 40 and 42 do not analyze extracorporeal blood pressure to derive the intravascular blood pressure in proximity of a suspected location of a blood flow restriction and compare the derived intravascular blood pressure to a standard. While the sensors 40 and 42 may sense the particular pressure that Polaschegg describes, they are not able to analyze this pressure in order to derive intravascular pressure. In other words, sensors 40 and 42 do not read on the "analyzing means" of the presently pending independent claims. Polaschegg does not compare any pressure with a standard value that would indicate whether the derived intravascular pressure is normal as required in the present invention, but rather normalizes the measured pressure pulse amplitudes so that they can be compared with each other and account for differences between systolic and diastolic pressure (see Col. 8, lines 16-56).

In contradistinction, the present invention does not measure pressure pulse amplitudes but rather derives the actual intravascular pressure (venous pressure) of the patient and is a robust enough process that measurement can be performed without turning off any machinery such as blood pumps or alternating the normal operation of the hemodialysis machine performing dialysis. The device and method of the present invention use an empirically determined formula that includes nonlinear dynamic measurements of the circuit resistances with corrections for blood

pump speed and hematocrit to determine the mean internal venous access pressure, i.e. the absolute intravascular pressure. The intravascular pressure is then divided by the mean arterial pressure to derive the ratio which is called Venus Access Pressure Ratio. The algorithm also compares the derived intravascular pressure ratio obtained during each treatment to a standard to indicate the presence of a significant stenosis. The standard is based on statistical analysis of patient data which established a correlation between the venous access pressure ratio (intravascular pressure) and clinical findings that indicate that the developing stenosis is a significant risk to the patient and requires referral for treatment.

The principles used for the system of the present invention were initially established by Besarab and Frinak and are cited in the background section of Polaschegg (col. 2 lines 31-46). Initially, the system was developed for measurement of static intra-access pressures by the dialysis staff; however, it required a significant amount of staff time for measurements and recording of the results. The development of the present invention of the algorithm for determination of the venous intra-access pressure while the blood pump was running allowed the measurements to be made without using staff time and for complete computerization of the system.

The present invention was developed using an *ex vivo* dialysis circuit containing human whole blood, while Polaschegg's initial testing was done with water because only pulse amplitude was analyzed. Human whole blood was used for the present invention in order to determine critical circuit resistances and to determine the changes is circuit pressures when the red blood cell concentration was varied over the range observed for dialysis patients. The device of the present invention is based on a mathematical model that incorporates all of the standard machine operating variables observed in the extracorporeal circuit during a patient's dialysis treatment and recorded in the medical record.

Pulse pressure and intravascular pressure are two very different measurements and do not provide the same information to a physician. The device of Polaschegg would not be able to detect a stenosis that the device of the present invention is able to detect through its calculation of intravascular pressure. A constant amplitude in pulse pressure can still be present with a change in absolute intravascular pressure, as in hypertensive and hypotensive patients. Under such conditions, Polaschegg's calculations and detections with the sensors would result in a conclusion that no stenosis is present, whereas the present invention would indicate a stenosis is present, enabling the patient to receive appropriate preventive treatment.

Therefore, since the Polaschegg patent does not disclose deriving intravascular blood pressure as set forth in the presently pending independent claims, the claims are patentable over the Polaschegg patent and reconsideration of the rejection is respectfully requested.

Claims 2, 6, 13, and 15-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Polaschegg in view of U.S. Patent No. 4,710,164 to Levin, et al. Specifically, the Office Action holds that Polaschegg discloses all of the limitations of the independent claims, but fails to disclose that a microprocessor is used to analyze the data where the derived intravascular blood pressure is compared to a standard using an algorithm. The Office Action holds that Levin, et al. teaches an automated hemodialysis system that uses a microprocessor for monitoring blood pressure. Therefore, the Office Action holds that it would have been obvious to one skilled in the art to have used a microprocessor similar to the one in Levin, et al. in a stenosis detection device similar to that of Polaschegg in order to monitor the extracorporeal blood pressure and for controlling the dialysis machine. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Polaschegg in view of Levin, et al. is respectfully requested.

As stated above, Polaschegg does not disclose all of the required elements of the independent claims of deriving intravascular pressure. Combining Polaschegg with Levin, et al. does not make up for the deficiencies therein. Adding a microprocessor to Polaschegg still does not enable one to derive intravascular pressure and compare this to a standard as required by the present invention, and neither is there any reason found in Polaschegg that indicates that the measurements of pressure pulse amplitude as disclosed therein are not sufficient to detect a stenosis.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: 10/29/08

CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

Date of Electronic Filing: 10/29/08

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Terry Horst